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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,175	12/26/2001	William J. Drasler		6071

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4100 Dynasty Drive
Minnetonka, MN 55345

EXAMINER

THALER, MICHAEL H

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 06/30/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/036,175

Applicant(s)
Drasler et al.

Examiner
Michael Thaler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 11, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-62 and 64 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-62 and 64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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Claim 62 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In line 4, "being attached to the blood vessel" defines the blood vessel (which is non-statutory subject matter) as being part of the claimed combination. This may be corrected by inserting "adapted to be" after "being".

Claims 35-62 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polansky (3,304,557). Polansky shows flexible strands 13 having axial componency interwoven with flexible strands 14 having circumferential componency forming at least a portion of a tubular wall and structural strands (15 or 16) interwoven along with the flexible strands, the structural strands (15 or 16) having a centerline (longitudinal axis within the cylinder defined by strands 15 or 16) that is located substantially in the center of the tubular wall (i.e. at the center axis of the tubular wall). The Polansky structural strands (15 or 16) are "substantially continuously" interwoven by said flexible strands in the sections 12 of the tube. The Polansky specification fails to specifically indicate that the structure will not significantly leak blood serum or blood cellular elements. However, Polansky does teach that the structure may be used as an artificial artery or vein (col. 1, line 58). It would have been obvious that a structure which performs this function would not significantly leak blood serum or blood cellular elements since a significant leak

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would destroy the intended function of conveying the blood. As to claim 36, Polansky discloses interwoven axial and circumferential flexible strands 13, 14 having a common tubular wall centerline (the longitudinal axis within the cylinder defined by strands 13, 14) and structural strands (15 or 16) having a centerline (the longitudinal axis within the cylinder defined by strands 15 or 16) that is substantially centered on the tubular wall centerline of the flexible strands 13, 14. As to claim 38, Polansky fails to disclose a bifurcated member. However, it is well known in this art to make arterial grafts bifurcated in order to conduct blood to two arterial branches. Making the Polansky tubular member bifurcated so that it also could perform this function would have been obvious. As to claims 44 and 45, Polansky fails to disclose the reinforcing structural strands 15 or 16 as being metal. However, it, is well known in this art to use metal as a reinforcing material for grafts since it is very strong. Using metal as the material for reinforcing structural strands 15 or 16 of Polansky would have been obvious for this reason. As to claim 57, the Polansky structural strands 15 or 16 which form the helix portion of the alternating rings and helix described in col. 5, lines 66-69 extend in an axial (as well as circumferential) direction. As to claims 61 and 62, Polansky fails to disclose the structural strands extending beyond an end of the tubular member to be attached to an attachment means. However, it is well known in

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this art to so construct attachment means on vascular grafts in order to provide a strong attachment between the graft and blood vessel. It would have been obvious to so construct the Polansky vascular graft so that it too would have this advantage. As to claim 64, Polansky discloses structural strands (15 or 16) interwoven substantially within the weave plane of the flexible strands 13, 14. The phrase "interwoven substantially within said weave plane" in claim 64, line 8 is considered to mean that the structural strands pass within the weave plane at least in portions thereof where the undulating structural strands cross into the weave plane. Figures 6, 7 and 8 of Polansky, for example, show structural strands 15 passing within the weave plane of strands 13, 14.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Note that Hogan (6,569,191) shows structural strand 30 within the weave plane of flexible strands 22, 26.

Applicant's arguments filed June 11, 2003 have been fully considered but they are not persuasive. The centerline as broadly defined in claims 35 and 36 may be considered the longitudinal axis of the tubular member. The imaginary cylinder defined by the structural strands (e.g. 660, 655) of applicant's invention appears to be larger than the imaginary cylinder defined by the flexible strands (635, 640) as seen in figure 15 of applicant's drawings.

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As seen in this figure, structural strand 655 lies above plane 675 of the flexible strands (635, 640) not only in the area of the crossover point 610 but also in the areas spaced therefrom. Further, Structural strand 660 does not lie below above plane 675 even in the area of the crossover point 610. In order for the flexible strands and structural strands to be coextensive (i.e. to have exactly the same diameter) the structural strands would have to pass under as well as over the plane 675 (which is not shown in figure 15). Further, the amount that the structural strands deviate from the plane 675 would have to be substantially the same both below and above the plane (which is also not shown in figure 15).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period

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for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703)308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
June 20, 2003



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731